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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,188	11/21/2001	Birgit Jordan	2481.1761-00	9429

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/989,188	JORDAN ET AL.	
	Examiner	Art Unit	
	Stacy B Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's preliminary amendment filed June 27, 2003 is acknowledged and entered. Claims 1-48 are pending and subject to the following restriction requirement.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20 and 47, drawn to a method for identifying a compound that modulates EVH1 binding activity, comprising the use of antibodies, classified in class 435, subclass 7.1.

II. Claims 21 and 22, drawn to a chemical compound, classified in class 530, subclass 300.

III. Claim 23, drawn to a method for treating various diseases, classified in class 435, subclass 4. Further restriction is required if this Group is elected. This is *not* a species election. Applicant must elect one disease for examination: cardiovascular disorders, inflammatory disorders or neoplastic cell/tissue changes.

IV. Claims 24 and 25, drawn to monoclonal antibody IE245, classified in class 424, subclass 130.1.

V. Claims 25 and 26, drawn to a monoclonal antibody IE273, classified in class 424, subclass 130.1.

VI. Claims 28-37, drawn to a solid surface coated with EVH1, classified in class 424, subclass 184.1.

VII. Claims 38-46 and 48, drawn to a method to identify a compound that modulates EVH1 binding activity, without the use of antibodies, classified in class 435, subclass 4.

The inventions are distinct, each from the other for the following reasons:

a) Groups I and VII are distinct methods. While some of the method steps are shared between the methods, one difference renders them distinct: the use of antibodies to identify the desired compound that disrupts EVH1 binding activity. A search for a method that uses antibodies will not necessarily reveal literature that speaks to a method that does not use antibodies, or vice versa. It would be a serious burden to search both methods due to the difference in method steps and reagents.

b) Groups (I and VII) and III are unrelated inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to separate methods. Groups I and VII are directed to discovering compounds that interfere with EVH1 binding, while the method of Group III is drawn to a method of treating disease. Treating disease would require that the compound to be administered be discovered already. Therefore, the methods are unrelated.

c) Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the

compound can be made synthetically. The compound may already be in existence and does not depend on the method of Group I for its production.

d) Inventions I and (IV, V and VI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products are two monoclonal antibodies and a solid surface coated with EVH1. The monoclonal antibodies can be used in methods of purifying proteins to which the antibodies bind to. The solid surface coated with EVH1 can be used to detect different types of antibodies and perform epitope mapping.

e) Inventions II and III are related as product and process of use. In the instant case the product can be used to purify antibodies in an immunoassay.

f) Inventions II, (IV and V) and VI are all unrelated inventions. The products are drawn to chemical compounds (including peptides), monoclonal antibodies and a solid surface coated with EVH1. Peptides and antibodies are structurally different and functionally different. The peptide of Group II will not encode the antibodies of Groups IV and V. The solid surface coated with EVH1 is not structurally similar in any way to the peptides and antibodies. These three product types are separately patentable.

g) Inventions (II, IV, V) and VII are unrelated. The method of Group VII does not require the compound of Group II, nor is it disclosed that the compound of Group II is discovered by the method of Group VII. The antibodies of Groups IV and V are not required to practice the method of Group VII.

h) Inventions III and (IV, V and VI) are unrelated. The method of Group III, treatment, does not require the monoclonal antibodies of Groups IV and V, nor the solid surface coated with EVH1 of invention VI.

i) Inventions IV and V are patentably distinct inventions. Both are drawn to monoclonal antibodies, however, they bind to different epitopes which renders their structure (variable regions) different in amino acid sequence. A search for the monoclonal antibody of Invention IV will not necessarily reveal the monoclonal antibody of Group V. A search for both antibodies would be a serious burden since they bind different epitopes.

j) Inventions VI and VII are related as product and process of use. In the instant case the solid surface coated with EVH1 could be used in the method of Group VII, although it is not specifically claimed. Nevertheless, the product could be used in a method to detect different types of antibodies and perform epitope mapping.

k) Restriction between treatment of disease/disorder types in claim 23, Group III, is required because the treatment of cardiovascular disorders, inflammatory disorders and neoplastic cell/tissue changes are high variant. A search of the literature for treatment of cardiovascular disorders would not necessarily reveal literature that discloses treatment of neoplastic disorders, or vice versa. These disorders are complex and would not likely be treated in the same manner as claimed or found in the same literature.

Because these inventions are distinct for the reasons given above and the literature search required for one group is not co-extensive, and therefore a serious burden, restriction for examination purposes as indicated is proper. Applicant is advised that the reply to this

requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product

claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

5. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Stacy B. Chen

Stacy B. Chen
December 23, 2004